



CERTIFICATE OF COMPLIANCE

This product has been manufactured in compliance with ISO 13485:2016 and Medical Device Single Audit Program (MDSAP) standards and meets Nova Biomedical product specifications.

Customer:	LIFESCAN
Description:	TEST STRIPS, STATSTRIP™ GLUCOSE, PACKAGED 18 BOXES OF 100 COUNT
Lifescan Purchase Order No.:	643744
Catalog Number:	42214
Nova Biomedical P/N	54515
One Touch P/N	02315302
Target Range (mg/dL) SD(mg/dL) /CV (%)	
30-50 ≤ 4 mg/dL	PASS / FAIL
51-110 ≤ 6.0%	PASS / FAIL
111-150 ≤ 5.0%	PASS / FAIL
151-250 ≤ 5.0%	PASS / FAIL
251-400 ≤ 5.0%	PASS / FAIL
Accuracy Criteria 1: Total within +/-12 mg/dL or +/- 12% of reference method ≥ 95%	PASS / FAIL
Accuracy Criteria 2: Total within +/-15 mg/dL or +/- 15% of reference method ≥ 98%	PASS / FAIL
Qty:	30,024
Lot No.	0323289249
Date of Mfg. (DOM):	2023 / 10 / 16 (YYYY/MM/DD)
Expiration Date:	2025 / 10 / 16 (YYYY/MM/DD)
Unique Device Identifier (UDI):	(01)20385480422141 (11)231016 (17)251016 (10)0323289249

Marc Browne
Quality Control Manager

10/25/23
Date

Nova Biomedical Corporation 200 Prospect St Waltham, MA 02454